

# EXHIBIT 6

GODFREY OAKLEY, JR., MD  
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<p>IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF ILLINOIS</p> <p>J.E., A MINOR, BY LINDA LEJEUNE, INDIVIDUALLY AS LEGAL CUSTODIAN AND NEXT FRIEND,</p> <p>Plaintiffs,</p> <p>vs.</p> <p>ABBOTT LABORATORIES, INC.,</p> <p>Defendant.</p> <p>DEPOSITION OF</p> <p>GODFREY P. OAKLEY, JR., M.D.</p> <p>February 21, 2014</p> <p>9:50 a.m.</p> <p>2000 Century Boulevard, NE Atlanta Marriott Century Center Atlanta, Georgia</p> <p>J. David Brown, RPR, B-1401</p> <p>Case No. 13-cv-326-SCW</p>		<p>INDEX OF EXAMINATION</p> <p>WITNESS: GODFREY P. OAKLEY, JR., M.D.</p> <p>Examination by Mr. Strain</p> <p>INDEX TO EXHIBITS</p> <p>Defendant's Exhibit Description Page</p> <p>1 Abbott Laboratories, Inc.'s Notice of Deposition of Godfrey P. Oakley, Jr., M.D. 6</p> <p>2 report by Dr. Oakley 7</p> <p>3 handwritten notes thru January 31, 2014 7</p> <p>4 PDR 1994 Depakote 193</p> <p>5 Memorandum of Telephone Conversation dated 10/29/82 18</p> <p>6 Ciba Foundation Symposium 181, Neural Tube Defects 195</p> <p>7 Teratogen Update: Valproic Acid 164</p> <p>8 Abbott Interoffice Correspondence dated 11/10/82 22</p> <p>9 MMWR dated August 26, 1983 49</p> <p>10 article by Rosa entitled Spina Bifida in Infants of Women Treated with Carbamazepine During Pregnancy 52</p> <p>11 MMWR dated October 29, 1982 63</p> <p>12 Letter to the Editor entitled Valproic Acid and Spina Bifida from The Lancet, November 13, 1982 80</p> <p>13 publication entitled Vallum: An Oral Cleft Teratogen? 100</p>	
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<p style="text-align: right;">Page 17</p> <p>1 A. I wrote an expert witness report.</p> <p>2 Q. For whom?</p> <p>3 A. For the plaintiffs.</p> <p>4 Q. And roughly when was that, sir?</p> <p>5 A. It was 2009, 2010, in that neck of the</p> <p>6 woods. Exact dates I don't recall.</p> <p>7 Q. And you provided that report to the</p> <p>8 plaintiffs?</p> <p>9 A. Yes.</p> <p>10 Q. Did you bring that here --</p> <p>11 A. I did not.</p> <p>12 Q. -- Dr. Oakley?</p> <p>13 Do you still have a copy?</p> <p>14 A. Sure.</p> <p>15 MR. STRAIN: Counsel, I'll call for the</p> <p>16 production of that report, please.</p> <p>17 Q. (By Mr. Strain) Dr. Oakley, when you met</p> <p>18 with the lawyers for the plaintiffs, whether the</p> <p>19 counsel present here or other counsel, were you</p> <p>20 given any documents by those counsel?</p> <p>21 A. I don't think I've gotten -- I think the</p> <p>22 answer is no.</p> <p>23 Q. Were you shown any documents by those</p> <p>24 counsel?</p> <p>25 A. Maybe one or two.</p>	<p style="text-align: right;">Page 19</p> <p>1 of the report that must have been MacMahon's report</p> <p>2 back to Abbott. Abbott had hired MacMahon.</p> <p>3 Q. Dr. MacMahon of Harvard --</p> <p>4 A. Exactly.</p> <p>5 Q. -- you're talking about?</p> <p>6 A. Exactly.</p> <p>7 Q. His report back to Abbott --</p> <p>8 A. Yes.</p> <p>9 Q. -- of that meeting?</p> <p>10 A. Yes.</p> <p>11 Q. And do you remember that meeting apart</p> <p>12 from the documents that you were shown?</p> <p>13 A. I remember it clearly, yes.</p> <p>14 Q. Now, Dr. MacMahon raised questions --</p> <p>15 first of all, did you know Dr. MacMahon before the</p> <p>16 meeting?</p> <p>17 A. Personally I didn't know him.</p> <p>18 Q. Did you know of him?</p> <p>19 A. I did.</p> <p>20 Q. Did you know of his reputation?</p> <p>21 A. I have his textbook on my shelf.</p> <p>22 Q. What's that textbook?</p> <p>23 A. Textbook of Epidemiology, Principles and</p> <p>24 Practices of Epidemiology.</p> <p>25 Q. He's a prominent authority in the field of</p>
<p style="text-align: right;">Page 18</p> <p>1 Q. And what were the one or two that those</p> <p>2 counsel showed you?</p> <p>3 A. I mean I asked about a report from a</p> <p>4 meeting that occurred in Atlanta because I was</p> <p>5 interested in what the report from that meeting had</p> <p>6 been from Professor MacMahon. I believe I saw part</p> <p>7 of that report there. Then I'm trying to remember,</p> <p>8 I don't remember other things that I would have seen</p> <p>9 at that meeting.</p> <p>10 Q. Well, Exhibit 5 to your deposition is an</p> <p>11 internal FDA document. I take it the lawyers for</p> <p>12 the plaintiffs showed you that?</p> <p>13 A. I may have seen this briefly, yes.</p> <p>14 Q. The lawyers showed it to you?</p> <p>15 A. Yes.</p> <p>16 Q. And when was that that the lawyers showed</p> <p>17 it to you?</p> <p>18 A. I think on one of the trips to Houston,</p> <p>19 probably the first one.</p> <p>20 Q. And what did you just refer to a moment</p> <p>21 ago? You referred to, whatever the exact words were</p> <p>22 you used, you referred to a memorandum of a meeting</p> <p>23 where Professor MacMahon was present.</p> <p>24 A. I think there was a meeting around this</p> <p>25 time that happened in Atlanta and I think I saw part</p>	<p style="text-align: right;">Page 20</p> <p>1 epidemiology in the United States and was in early</p> <p>2 1980s, correct?</p> <p>3 A. That's correct.</p> <p>4 Q. One of the most prominent in the early</p> <p>5 1980s, correct?</p> <p>6 A. That's correct.</p> <p>7 Q. One of the most prominent and respected</p> <p>8 authorities in the field of epidemiology, correct?</p> <p>9 A. Yes.</p> <p>10 Q. Now, you say you remember the meeting</p> <p>11 clearly. Do you remember Dr. MacMahon expressing</p> <p>12 skepticism or concerns about the quality of the data</p> <p>13 that came out of France and the need to check to see</p> <p>14 whether it was reliable?</p> <p>15 A. I do not remember that.</p> <p>16 Q. Did you see that in his report?</p> <p>17 MR. WILLIAMS: You cut him off.</p> <p>18 Q. (By Mr. Strain) Had you finished your</p> <p>19 answer, sir?</p> <p>20 A. No. What I remember most distinctly about</p> <p>21 that was I presented evidence to him and in the end</p> <p>22 I said this is, like all studies, not -- there are</p> <p>23 no perfect studies but the findings here are so</p> <p>24 strong, I find this convincing and I understood that</p> <p>25 he agreed with me.</p>



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<p style="text-align: right;">Page 25</p> <p>1 ways in which bias in ascertainment of malformation 2 or in recording of exposure can lead to a distorted 3 set of data? 4 A. Yes. 5 Q. Do you remember that Dr. MacMahon 6 expressed to you that he needed to explore or 7 thought it was appropriate and reasonable to explore 8 whether bias in ascertainment about malformation or 9 recording of exposure had led to a distorted set of 10 data? 11 A. I don't remember that he said that, no, 12 sir. 13 Q. Do you believe he did not? 14 A. To me? 15 Q. Yes. 16 A. I don't recall that he said that, no. 17 Q. Do you remember enough about that meeting 18 to say that he did not say it to you or are you 19 simply saying you don't recall whether or not he 20 said it? 21 A. I just simply don't recall. 22 Q. Now, you would agree it would have been 23 reasonable for Dr. MacMahon to go to Lyon to 24 interview the researchers to obtain more information 25 so that he could make a judgment about whether those</p>	<p style="text-align: right;">Page 27</p> <p>1 A. So say the question again, please. 2 Q. Can you tell me whether this Exhibit 8 3 having read it is consistent or inconsistent with 4 your memory of your meeting with Dr. MacMahon at CDC 5 at the end of October of '82? 6 MS. BRAHMBHATT: Same objection. 7 A. What I read here is that he more or less 8 agreed with what we concluded at that meeting. 9 That's what I see here. He said he agreed basically 10 that the relative risk was about what we said it was 11 and so I thought that it is confirming of his -- my 12 interpretation of his comments at that meeting. 13 Q. When you learned of the data from Lyon you 14 had gone to interview the researchers, correct? 15 A. I did. 16 Q. You thought that was necessary in order to 17 determine the reliability of the data, correct? 18 A. I did not feel like I needed to do that to 19 justify the reliability of the data. I had no 20 reason to suggest -- to think that the birth defects 21 registry that I had worked with for these people for 22 a number of years was anything but standard okay 23 registry. 24 Q. Why did you then go to interview them 25 about the data?</p>
<p style="text-align: right;">Page 26</p> <p>1 biases had distorted the set of data? 2 MR. WILLIAMS: Objection. This is way 3 outside of his designated area of expertise and 4 so we object. 5 Q. (By Mr. Strain) Please answer, Doctor. 6 A. Restate the question, please. 7 Q. Do you agree that it would have been 8 reasonable of Dr. MacMahon to go to Lyon to 9 interview the researchers to determine whether those 10 biases had led to a distorted set of data? 11 MR. WILLIAMS: Same objection. 12 Q. (By Mr. Strain) That was reasonable for 13 him to have wanted to do that, correct? 14 A. Yes. 15 Q. Now, having read this document, which is 16 Exhibit 8, can you tell me whether it is consistent 17 or inconsistent with your memory of your meeting 18 with Dr. MacMahon and the Abbott representatives at 19 CDC? 20 MS. BRAHMBHATT: I'm actually going to 21 object to the form and the completion of this 22 document. You're asking Dr. Oakley to testify 23 to a five-page document and we only have three 24 pages in front of us. 25 Q. (By Mr. Strain) Please answer, Doctor.</p>	<p style="text-align: right;">Page 28</p> <p>1 A. I went just to see the registry and to 2 meet with Dr. Robert. 3 Q. Why my question was? 4 A. Well, to look at some of the records and 5 they seemed to be -- the ones I looked at seemed to 6 be straight up. 7 Q. Why did you want to look at some of the 8 records to see if they were straight up? 9 A. I think I was close, we were going to a 10 second meeting, I was not far away, it was something 11 I could do. 12 Q. But why did you want to? That was my 13 question. 14 MS. BRAHMBHATT: I think that's asked and 15 answered. 16 MR. STRAIN: Asked but not answered. 17 Q. (By Mr. Strain) Please answer, Doctor. 18 MS. BRAHMBHATT: To the best of your 19 abilities, Dr. Oakley. 20 A. I mean the primary reason for going was to 21 look at and see some sense of what the registry was 22 like. 23 Q. And why did you want to do that? 24 A. As I said, I was close, I know Professor 25 Elisabeth Robert, I had never seen her registry, I</p>

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<p style="text-align: right;">Page 29</p> <p>1 wanted to see that. It was a very exciting time of 2 excitement about this new cause of birth defects and 3 I wanted to see them. 4 Q. You said you looked at records to 5 determine whether they were straight up. What did 6 you mean by that? 7 A. I mean I looked -- the main thing that I 8 think I wanted to know is how they collected the 9 data and did they have a question and he did have a 10 question and that was what I looked at was the 11 generalities of these -- how the registry ran and to 12 understand it better. 13 Q. What did you mean when you said you saw 14 that the records were straight up? What did you 15 mean by that? 16 A. Well, it is a birth defects registry. So 17 how are the data collected, what was the question on 18 the questionnaire, was there a question about 19 anticonvulsants on the questionnaire. Yes, there 20 was a question about anticonvulsants on the 21 questionnaire just as Elisabeth had said that there 22 was. So that's what I mean. That seemed to me to 23 be quite ordinary and reasonable registry activity 24 and form. 25 Q. Did you do any research concerning</p>	<p style="text-align: right;">Page 31</p> <p>1 I have searched the way you do a standard literature 2 search, many different ways. 3 Q. So after you were contacted by the 4 lawyers, you did do a literature search? 5 A. Yes. 6 Q. Do I understand you correctly? 7 A. Yeah. Sure. 8 Q. And what did you search for? 9 A. I searched for valproic acid in birth 10 defects. 11 Q. And you did that on PubMed or something 12 else? 13 A. Yeah. PubMed, yes. 14 Q. And did you download and copy articles? 15 A. I mean I had some of them, so I don't 16 remember how many -- the new stuff I may have 17 downloaded, yes. 18 Q. Were any articles from the medical 19 literature supplied to you by the lawyers for 20 plaintiffs? 21 A. I had mine. 22 Q. That's not my question. 23 A. No. 24 Q. Were any documents, articles from the 25 medical literature supplied to you by the lawyers?</p>
<p style="text-align: right;">Page 30</p> <p>1 valproate and birth defects in connection with this 2 litigation after you were contacted by the lawyers 3 for plaintiffs? 4 A. Did I do any research -- 5 Q. Yes, sir. 6 A. -- after then? 7 Q. Yes, sir. 8 A. I was in the midst of doing some research 9 on this and trying to determine what was the current 10 pattern of use among women at reproductive age, yes. 11 But I was working on that before I was contacted. 12 Q. You say at page 3 of your report that 13 you're being compensated at \$500 an hour for 14 research, meetings, telephone conferences, 15 et cetera. 16 A. Yep. 17 Q. What I'm asking is what research did you 18 do that you were compensated for? 19 A. Mostly literature research. I mean just 20 making sure that I have the papers to look at. 21 Q. And where did you obtain the papers that 22 you -- 23 A. I had retained them many different places, 24 searching NIH -- I mean National Institute of 25 Medicine searches from the library there. You know,</p>	<p style="text-align: right;">Page 32</p> <p>1 A. Not that I didn't already have. 2 Q. What articles from the medical 3 literature -- 4 A. I think -- 5 Q. -- were supplied to you -- 6 A. -- we got yesterday -- 7 Q. -- by the lawyers? 8 A. -- the Sever -- Lammer Sever article. I 9 think it is listed as an exhibit here. 10 Q. Any others that the lawyers gave you? 11 A. You know, I don't recollect any others. 12 Q. Now, did you in connection with this 13 litigation since you first started talking to the 14 lawyers, which was early in 2012, did you talk to 15 anyone, any other doctors, healthcare professionals 16 about valproate and birth defects? 17 A. Students I talk to about birth defects and 18 valproic acid all the time. 19 Q. Anyone else? 20 A. I was an expert witness or I wrote a 21 letter for another case so I did that, yeah, but I 22 didn't have a deposition. 23 Q. You wrote a letter for another case about 24 valproate? 25 A. Yes, exactly.</p>

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<p style="text-align: right;">Page 33</p> <p>1 Q. And that's the European case you talked 2 about? 3 A. No. A different one. 4 Q. What case was that? 5 A. A case in Pennsylvania. 6 Q. What was the name of that case? 7 A. I'm trying to remember. And I'm sorry but 8 right now I can't remember but maybe later in the 9 day I will remember. 10 Q. You wrote that letter to whom? 11 A. To the attorney. 12 Q. Who was that? 13 A. Giordana. 14 Q. Pardon me? 15 A. Patricia Giordana. 16 Q. And was that letter you wrote about 17 valproate. 18 A. It was. 19 Q. And what did you understand the purpose of 20 that letter was? 21 A. The purpose of that letter was to state my 22 opinion about whether valproic acid caused 23 spina bifida and the second letter -- there were two 24 letters. The second letter was on what are the 25 long-term educational needs for people with</p>	<p style="text-align: right;">Page 35</p> <p>1 A. Yep. 2 Q. Did you retain any documents, internal CDC 3 documents when you left? 4 A. I mean there were copies. I had copies of 5 things, yes. 6 Q. What things? 7 A. I actually don't remember. They're packed 8 in boxes and I haven't unpacked them. So I have no 9 idea. I just can't answer the question. 10 Q. So just generically what were those 11 things? 12 A. Well, I had my files, my personal files 13 there, you know. 14 Q. I guess I'm a little surprised. As a CDC 15 employee are you permitted to take with you internal 16 documents from the CDC when you leave? 17 A. Well, copies, yes. There's not any 18 problem with that. You have to leave the originals 19 but the copies, yes. 20 Q. So you brought copies of internal CDC 21 memoranda; is that correct? 22 MS. BRAHMBHATT: Objection, form. 23 A. As I say, I haven't looked at them in a 24 very long time. I can't tell you what was in those. 25 Q. (By Mr. Strain) But when you left CDC in</p>
<p style="text-align: right;">Page 34</p> <p>1 spina bifida. 2 Q. And did you meet with Ms. Giordana as 3 well? 4 A. I don't think we did actually. 5 Q. Have you billed the counsel -- Mr. Fibich, 6 Mr. Williams, any other counsel -- for any of the 7 time reflected on Exhibit 3? 8 A. I haven't billed anybody yet. 9 Q. When you do bill and receive the money, 10 will that money go to you, to Emory, or to some 11 other place? 12 A. It will come to me. 13 Q. The report you did in this case as your 14 own personal report, it does not purport to be the 15 work or the opinions of the CDC; is that correct? 16 A. That's correct. 17 Q. It is your own personal opinions of 18 Dr. Oakley and that's all, correct? 19 A. Yes. 20 Q. You're not speaking for the CDC in this 21 testimony or this case, you are just speaking for 22 yourself; is that correct? 23 A. That's correct. 24 Q. You left the CDC in 1998 I believe; is 25 that correct?</p>	<p style="text-align: right;">Page 36</p> <p>1 1998, you packed documents into boxes; is that 2 right? 3 A. (Nods head affirmatively.) 4 Q. Yes? 5 A. Yes. 6 Q. Roughly how many boxes? 7 A. Oh, I don't know. I'd say 25. 8 Q. 25 boxes. Where are those 25 boxes? 9 A. They're at my house. 10 Q. Is it your testimony you haven't opened 11 any of the 25 in the last 15 or 16 years? 12 A. I actually have not. 13 Q. Are you relying for your opinions in this 14 case on any CDC documents other than what may have 15 been published in the medical literature? 16 A. No. Only the MMWR article that's in the 17 package here. 18 Q. Are you relying on any Abbott internal 19 documents for your testimony in this case? 20 A. No, sir. 21 Q. You have never been retained by Abbott for 22 any reason; is that correct? 23 A. I believe that to be true. 24 Q. You have never consulted for Abbott or 25 spoken for Abbott?</p>

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<p style="text-align: right;">Page 57</p> <p>1 Q. During all of the eighties and all of the 2 nineties up until 1998 you were in a position of 3 responsibility at the Center for Disease Control for 4 birth defects, weren't you? 5 A. That's correct. 6 Q. Were you the highest official at the 7 Center for Disease Control involved with birth 8 defects? 9 A. I was. 10 Q. If anyone was going to put in writing a 11 recommendation that any new AED should have a 12 registry, it should have been you, correct, anyone 13 from CDC, right? 14 A. Yes. 15 Q. Did you tell anyone who worked for you to 16 publish or put in writing that any new AED should 17 have a registry? 18 A. I don't recall having done that. 19 Q. Doctor, we've already agreed that the CDC 20 publishes the MMWR every week, correct? 21 A. That's correct. 22 Q. It puts out information to the medical 23 community on a weekly basis, correct? 24 A. Yes. 25 Q. And that MMWR was available to you to make</p>	<p style="text-align: right;">Page 59</p> <p>1 such a thing that it would have been accepted by the 2 editor of the MMWR. It's just not -- it wasn't 3 some -- the MMWR is there to alert clinicians and 4 public health to existing and new problems. That's 5 its primary raison d'être. 6 Q. Doctor, in Exhibit 9 in the MMWR it talks 7 about a registry in the last paragraph, correct? 8 A. It does. 9 Q. Did you or anyone working for you at CDC 10 write anything else about an AED registry other than 11 that and one other MMWR from October of '82? 12 A. Not that I am aware of. 13 Q. Do you dispute, Doctor, that carbamazepine 14 causes spina bifida? 15 MS. BRAHMBHATT: Objection, form. 16 A. I didn't come prepared to discuss that. 17 Q. (By Mr. Strain) Do you believe that 18 carbamazepine causes spina bifida? 19 MS. BRAHMBHATT: Objection, form. 20 A. I would have to look at the data again. 21 Clearly the newer data suggests that valproic acid 22 is far and away the cause of spina bifida for the 23 AEDs. 24 Q. (By Mr. Strain) Well, I'm just asking 25 about your time at the CDC, Doctor, in charge of</p>
<p style="text-align: right;">Page 58</p> <p>1 any recommendation you believed should be made about 2 registries, correct? 3 A. It would be a very unusual MMWR to put 4 something about establishing a registry in the -- 5 for the FDA. That's the FDA's business. 6 Q. What is the FDA's business? 7 A. Our business was to try to find the causes 8 of birth defects wherever they came from. That's 9 why we ran the birth defects prevention registry and 10 why we did studies to find -- to look for causes. 11 Q. Doctor, if you believed that a company 12 putting out a new AED should have a registry, the 13 MMWR was available to you to put that recommendation 14 in writing, correct? 15 A. I have no recollection of anybody at CDC 16 ever having used the MMWR for such a recommendation. 17 Q. That wasn't my question. My question was 18 it was available to you if you wished to use it to 19 make such a recommendation? 20 A. I don't believe -- 21 MS. BRAHMBHATT: Object to form -- 22 A. I don't believe -- 23 MS. BRAHMBHATT: -- asked and answered. 24 Q. (By Mr. Strain) Go ahead, Doctor. 25 A. I don't believe that even if I had written</p>	<p style="text-align: right;">Page 60</p> <p>1 birth defects for the United States Center for 2 Disease Control, did you focus on carbamazepine as a 3 cause of spina bifida at least after the FDA's study 4 reported in Exhibit 10? 5 A. I will tell you that during this time our 6 primary focus was on trying to determine whether 7 folic acid or another vitamin prevents spina bifida 8 or not. And shortly after this time we learned that 9 it did and I was working overtime on trying to get 10 folic acid into women so we could prevent this birth 11 defect. 12 Q. After the FDA study you did not focus on 13 finding that carbamazepine caused spina bifida, does 14 that mean you did not focus on carbamazepine as a 15 cause of spina bifida? 16 A. I would say that while I was at the CDC 17 during these years I was focused primarily on 18 dealing with this huge, huge new possible important 19 public health event that a vitamin would prevent 20 most of spina bifida. And so there were potentially 21 many other associations with this drug or that drug 22 or this environmental agent that if it didn't, 23 somebody bring it to me in a way in which it seemed 24 to be more important, I wouldn't have paid much 25 attention to it.</p>

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<p style="text-align: right;">Page 61</p> <p>1 Q. You said you believed that the 2 manufacturer of any new AED should have a birth 3 defect registry. How many do, Doctor? 4 A. My last recollection is that there are 5 about four that have done that. 6 Q. What are those four? 7 A. I don't recall their names right now. 8 Q. So your testimony is there are four 9 antiepileptic drugs with birth defect registries? 10 A. Pregnancy registries, yeah. New ones, 11 yeah. 12 Q. And you don't remember what any of them 13 are? 14 A. I didn't come prepared to answer that 15 question. I remember I have read some of the papers 16 and I know that they did exist -- do exist. 17 Q. How many existed before 1995 or let's say 18 before 1997? 19 A. Tell me what the question is again, 20 please. 21 Q. How many manufacturer pregnancy registries 22 for AEDs existed before 1997? 23 A. I don't know of any. 24 Q. Doctor, is carbamazepine a teratogen? 25 MS. BRAHMBHATT: Objection, form.</p>	<p style="text-align: right;">Page 63</p> <p>1 yes. 2 Q. Being a human teratogen? 3 A. Yeah. 4 Q. Phenobarbital? 5 A. Let's so but some concern. 6 Q. Phenytoin? 7 A. Yes. 8 Q. Human teratogen? 9 A. Certainly concerned about that, yes. 10 Q. Primidone? 11 A. Yes. 12 Q. Human teratogen? 13 A. Yes. 14 Q. Did you contact the manufacturer of any of 15 those four just listed -- carbamazepine, 16 phenobarbital, phenytoin, or primidone -- and ask, 17 request, or advise them to start a pregnancy 18 registry? 19 A. No. 20 Q. Doctor, let's look at the other MMWR that 21 we just made reference to. We have marked, just to 22 orient you, Doctor, the August of '83 MMWR as 23 Exhibit 9. We'll mark as Exhibit 11 the October of 24 '82 MMWR. 25 (Defendant's Exhibit 11 was marked</p>
<p style="text-align: right;">Page 62</p> <p>1 A. I am not prepared to answer that right 2 now. 3 Q. (By Mr. Strain) You don't know? 4 MS. BRAHMBHATT: Objection, form. 5 A. As I said, before I would give an answer I 6 would like to review the data and have a chance to 7 think about it more than I've had a chance to do at 8 this point. 9 Q. (By Mr. Strain) Were all the AEDs in the 10 1990s teratogens, Doctor? 11 A. That's a tough question to answer. 12 Certainly there was concern about many of the 13 different anticonvulsants some of which are not used 14 as much anymore and the question becomes what is the 15 safest one of these and what are the size of the 16 risk and so on. 17 Q. Well, my question was were all the 18 antiepileptic drugs available for use in the 1990s 19 human teratogens; do you know? 20 MS. BRAHMBHATT: Objection, form. 21 A. It is always tough to answer a question 22 that says all. 23 Q. (By Mr. Strain) Well, I'll give you five. 24 Carbamazepine? 25 A. There was suspicion about carbamazepine,</p>	<p style="text-align: right;">Page 64</p> <p>1 for identification.) 2 Q. (By Mr. Strain) Did you write this, 3 Doctor, the editorial note? 4 A. I certainly would have been involved in 5 writing it and reviewing it, yes. 6 Q. It says: A registry of women currently 7 taking valproic acid during pregnancy is being 8 established. 9 A. Yes. 10 Q. I think that's something you made 11 reference to before, Doctor. Tell me what that 12 referred to, the registry that was being currently 13 established by CDC. 14 A. It basically was we had hoped to set up a 15 registry if people reported to us. And you see 16 there's a request here for physicians to send this 17 exposed women -- women who had been exposed in 18 pregnancy. 19 Q. And that phone number the physicians were 20 to call was a CDC phone number, correct? 21 A. That's correct. 22 Q. Whose phone number was that? 23 A. I think it was probably in my office but I 24 don't know for sure. 25 Q. And back at Exhibit 9, do you have that</p>

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<p style="text-align: right;">Page 65</p> <p>1 one still, Doctor?</p> <p>2 A. Yes.</p> <p>3 Q. If you would turn to the last paragraph of</p> <p>4 that it says: CDC is assembling a registry of women</p> <p>5 taking valproic acid during pregnancy. And it asks</p> <p>6 physicians to call another area code 404 number,</p> <p>7 correct?</p> <p>8 A. Yep.</p> <p>9 Q. Whose phone number was that?</p> <p>10 A. I would assume it is in our branch. I</p> <p>11 don't know exactly what the number is.</p> <p>12 Q. Well, both MMWRs asks physicians to write</p> <p>13 to the Birth Defects Branch of the CDC, correct?</p> <p>14 A. Correct.</p> <p>15 Q. You were the chief of that branch in</p> <p>16 1982 --</p> <p>17 A. That's true.</p> <p>18 Q. -- and 1983, correct?</p> <p>19 A. Yes.</p> <p>20 Q. What did you do with the data and the</p> <p>21 information when physicians called in?</p> <p>22 A. We got so few of those, we didn't do</p> <p>23 anything.</p> <p>24 Q. How many did you get?</p> <p>25 A. I actually don't recall. I would guess</p>	<p style="text-align: right;">Page 67</p> <p>1 Q. Were you a fellow of the American College</p> <p>2 of Pediatrics?</p> <p>3 A. It's the American Academy but yes.</p> <p>4 Q. Did you reach out to your own organization</p> <p>5 of which you were a fellow and encourage them to</p> <p>6 have pediatricians call the CDC to report</p> <p>7 pregnancies of women taking valproic acid?</p> <p>8 A. We did not.</p> <p>9 Q. And you believe you got less than ten</p> <p>10 physicians that actually called in information?</p> <p>11 A. That's true.</p> <p>12 Q. And what did you do with the information</p> <p>13 that was called in?</p> <p>14 A. I actually don't recall. I mean, you</p> <p>15 know, our thoughts were that this has been shown to</p> <p>16 be a human teratogen and so I was busy and our group</p> <p>17 was working primarily on other things. If it</p> <p>18 worked, it worked. But if it didn't work, it didn't</p> <p>19 work.</p> <p>20 Q. Well, what was the purpose in CDC wanting</p> <p>21 to establish a registry?</p> <p>22 A. In order to learn what might be other</p> <p>23 problems related to this exposure.</p> <p>24 Q. Problems other than spina bifida?</p> <p>25 A. Yes.</p>
<p style="text-align: right;">Page 66</p> <p>1 less than ten. I don't remember.</p> <p>2 Q. Well, in October of '82 you said a</p> <p>3 registry is being established and in August of</p> <p>4 '83 you said CDC is assembling.</p> <p>5 A. We were still trying but it didn't go very</p> <p>6 far.</p> <p>7 Q. What were you doing to try to assemble</p> <p>8 this registry --</p> <p>9 A. I think --</p> <p>10 Q. -- other than giving out a phone number?</p> <p>11 A. I think --</p> <p>12 MS. BRAHMBHATT: Objection, form.</p> <p>13 A. -- that's it.</p> <p>14 Q. (By Mr. Strain) Did you reach out to any</p> <p>15 physician organizations, professional organizations</p> <p>16 of neurologists or obstetricians?</p> <p>17 A. I don't believe we did that.</p> <p>18 Q. Or pediatricians?</p> <p>19 A. I don't think so.</p> <p>20 Q. You were a member of a professional</p> <p>21 organization of pediatricians in 1982 and 1983,</p> <p>22 weren't you?</p> <p>23 A. I was.</p> <p>24 Q. What professional association was that?</p> <p>25 A. American Academy of Pediatrics.</p>	<p style="text-align: right;">Page 68</p> <p>1 Q. You believed that spina bifida there was</p> <p>2 already enough information that was published and</p> <p>3 put in the warning label, that was taken care of?</p> <p>4 MS. BRAHMBHATT: Objection, form.</p> <p>5 Q. (By Mr. Strain) Is that correct?</p> <p>6 A. I believe that valproic acid since 1982</p> <p>7 was a cause of human birth defects.</p> <p>8 Q. Well, not my question. Did you believe in</p> <p>9 1982 on the subject of spina bifida that it was</p> <p>10 established that valproic acid was a cause of</p> <p>11 spina bifida in the range of 1 to 2 percent and that</p> <p>12 information had been published, it was in the</p> <p>13 warning label, and the registry was focused on --</p> <p>14 the CDC registry you wanted to establish was focused</p> <p>15 on other birth defects?</p> <p>16 MS. BRAHMBHATT: Objection, form.</p> <p>17 A. Yes.</p> <p>18 Q. (By Mr. Strain) Now, did you ask Abbott to</p> <p>19 establish a registry?</p> <p>20 A. I did not.</p> <p>21 Q. Did anyone to your knowledge?</p> <p>22 A. I don't know.</p> <p>23 Q. Did anyone at CDC to your knowledge?</p> <p>24 A. I don't think so.</p> <p>25 Q. Did anyone at FDA to your knowledge?</p>

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1 A. I wouldn't know about FDA's business.  
2 Q. You say in your report that: The effort  
3 to establish the registry was not pursued for lack  
4 of resources. Do you remember that phrase?  
5 A. I do.  
6 Q. When did you decide to abandon that -- was  
7 it your decision to abandon the effort to establish  
8 a valproate registry?  
9 A. I think it just faded away. People didn't  
10 come in. We didn't have money to do it. We didn't  
11 have money to go out and contact organizations and  
12 try to round up exposures.  
13 Q. I got to ask you about that, Doctor. How  
14 much money would it take to send a letter to a  
15 professional organization?  
16 A. You have to have somebody dedicated to do  
17 this. So it would take more than we felt like we  
18 could spend on the issue.  
19 Q. You had a doctor who was working in this  
20 field, didn't you, named Dr. Cragen?  
21 A. Yes, we had -- yep.  
22 Q. And how many doctors worked under you in  
23 the Birth Defects Branch in the early eighties or  
24 late eighties?  
25 A. Probably 20.

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1 Q. 20. Did you ever think to ask any one of  
2 those doctors to contact professional organizations  
3 of neurologists or obstetricians or pediatricians to  
4 encourage their member doctors to report pregnancies  
5 to the CDC valproic acid pregnancy registry?  
6 MS. BRAHMBHATT: Form.  
7 A. Our primary job was to run birth defects  
8 registries, not to run exposure registries. So  
9 that's where our people were spent.  
10 Q. (By Mr. Strain) Did you ever do what I  
11 just asked you about?  
12 A. And that is?  
13 Q. Direct a doctor to contact professional  
14 organizations of neurologists, obstetricians, or  
15 pediatricians to report to the CDC valproic acid  
16 registry?  
17 A. No.  
18 MS. BRAHMBHATT: We've been going for over  
19 an hour. Can we take a quick break?  
20 MR. STRAIN: Sure. Let me pursue  
21 something for just a couple more minutes.  
22 MS. BRAHMBHATT: Okay.  
23 Q. (By Mr. Strain) You would categorize what  
24 you were trying to start as an exposure registry I  
25 take it; is that right?

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1 A. Yes.  
2 Q. And what you said you were doing or  
3 focusing on was birth defects registries --  
4 A. Yes.  
5 Q. -- is that correct?  
6 A. Yes.  
7 Q. Does that mean the Atlanta registry?  
8 A. Yes, the Atlanta registry for sure.  
9 Q. And what others?  
10 A. Well, the CDC -- it depends upon what year  
11 you're talking about. But we encouraged the  
12 establishment of birth defects registries by state  
13 health departments and over the years a number of  
14 state health departments established those kinds of  
15 registries.  
16 Q. And what about the 1,200 hospital  
17 registry?  
18 A. That was one of our registries also, yes,  
19 during that time.  
20 Q. The time we're talking about the 1980s?  
21 A. Yeah. It was coming and going but I think  
22 it was still active in the eighties. It began to  
23 wind down late eighties, early nineties.  
24 Q. Why did it wind down?  
25 A. The PC.

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1 Q. What's that mean?  
2 A. What it means is that we bought those data  
3 from a company that processed hospital records and  
4 when cheaper computers came around hospitals didn't  
5 send their records off to a place in Michigan to  
6 have them processed. I'm assuming we're talking  
7 about the same thing.  
8 MR. STRAIN: We'll clarify that. But your  
9 counsel has suggested a break now and that's  
10 fine.  
11 (A recess was had.)  
12 Q. (By Mr. Strain) Back on the record,  
13 Doctor. Doctor, the two letters you did for  
14 Ms. Patricia Giordana that you referred to earlier,  
15 were they also shown to the lawyers for the  
16 plaintiffs in this litigation?  
17 A. I don't recall. I think I told them that  
18 I had done it but I don't recall sharing the letters  
19 with them. I just don't remember. I don't think  
20 so.  
21 Q. The registry we were talking about before  
22 the break, the CDC registry that you wrote about CDC  
23 establishing in the two MMWR reports. So are we  
24 with me what we're talking about, Doctor?  
25 A. I think so.

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<p style="text-align: right;">Page 73</p> <p>1 Q. Now, had you formulated a reporting form 2 for that? 3 A. I don't think so. 4 Q. Had you written out a protocol for how the 5 analysis would be done? 6 A. We did not. 7 Q. Did you consult with a statistician to 8 determine how the analysis should be done? 9 A. We were waiting to see if the cases were 10 coming in. 11 Q. Had you made any power calculations to 12 determine how many cases you would need to have 13 reported in order to get meaningful data? 14 A. Usually these registries are open-ended. 15 Q. So my question was had you made any power 16 calculations to determine how many exposures you 17 would need to have in order to get any meaningful 18 results? 19 A. We didn't. 20 Q. Not having done power calculations, had 21 you made any estimate of how many cases you would 22 have to have reported in order to get meaningful 23 results? 24 A. Anytime we thought about a study one would 25 be thinking of power calculations. This was a</p>	<p style="text-align: right;">Page 75</p> <p>1 correct? 2 A. That is correct. 3 Q. You know that there is an issue in any 4 birth defects registry of sufficient enrollment in 5 order to get meaningful -- in order to make analysis 6 of the results meaningful, correct? 7 A. Sure. 8 Q. And what is that issue, Doctor? 9 A. I am not sure I understand. 10 Q. What is the issue? Unless there's 11 sufficient enrollment, why is it that any results 12 from the registry would not result in a meaningful 13 analysis? 14 MS. BRAHMBHATT: Objection, form. 15 A. Again I'm not sure that I have gotten your 16 question. 17 Q. (By Mr. Strain) Have you ever formulated a 18 registry from the beginning, you, Dr. Oakley? 19 A. I certainly have worked with registries a 20 lot so I know that part of them. But having 21 established one de novo, no. I suppose I asked 22 Dr. Lammer to start a registry on Accutane, exposed 23 babies, and he did do that and so on. But that was 24 mostly his project. 25 Q. Dr. Lammer's project, not yours?</p>
<p style="text-align: right;">Page 74</p> <p>1 registry which you take -- you were just taking as 2 they came and you never know how many are going to 3 come. For example, we did one with congenital 4 rubella immunizations and we wanted to know how 5 many -- it was actually another part of CDC but we 6 consulted with them -- we'd want to know if there 7 five or if there were ten or if there were 20. And 8 as it grows, the power becomes better. And so it's 9 a pretty standard thing to take what comes and make 10 the most sense out of it as you can as it goes 11 along. 12 Q. I guess my question is a little different. 13 You referred to power calculations in your last 14 answer. Of course I had it in my question as well. 15 But did you have in mind in the early 1980s how many 16 pregnancies would have to be reported before you 17 would get any meaningful analysis from those 18 reports? 19 A. As I said earlier, the idea of setting 20 this registry up was the idea to take advantage of 21 exposures that might continue. Frankly I didn't 22 think there would be very many more exposures. 23 Q. So you did not have any number of reports 24 in mind that were necessary in order to get 25 meaningful analysis or data from it; is that</p>	<p style="text-align: right;">Page 76</p> <p>1 A. Well, he worked for me for a while and 2 then he left and went and worked for Dr. Holmes and 3 then finished the project up there. 4 Q. Now, how would you go about if you were 5 establishing a registry, which I understand you have 6 not done de novo as you have said, how would you go 7 about doing that? 8 A. Well, you'd have to find exposures -- are 9 you talking exposure registry or birth defects 10 registry? 11 Q. What's the difference? 12 A. Well, the birth defects registry my 13 definition of that is you collect cases of birth 14 defects hopefully that have occurred within the 15 population. What we did in Atlanta, we tried to 16 find in the confines of metropolitan Atlanta all the 17 babies born with birth defects so we could make a 18 judgment about what the incidence was and whether it 19 was going up or down and it also provided cases to 20 do case control studies which would be what has now 21 around the country are now six or eight of these 22 that worked together in a large collaborative 23 fashion. That is different from an exposure 24 registry where what you would do is you would find 25 people exposed and then go forward to try to figure</p>

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<p style="text-align: right;">Page 77</p> <p>1 out what would be any adverse effects from that</p> <p>2 exposure.</p> <p>3 Q. And what was the rubella registry?</p> <p>4 A. The rubella registry was an exposure</p> <p>5 registry. It was a registry of women who had</p> <p>6 been -- who had taken the rubella vaccine while they</p> <p>7 were inadvertently pregnant.</p> <p>8 Q. And that was a registry established by</p> <p>9 CDC?</p> <p>10 A. It was in the immunization part of CDC,</p> <p>11 yes.</p> <p>12 Q. Did any manufacturer provide the funds for</p> <p>13 that?</p> <p>14 A. I don't think so.</p> <p>15 Q. Was any manufacturer asked by CDC to</p> <p>16 establish a rubella registry?</p> <p>17 A. I have no idea.</p> <p>18 Q. It was focused on the rubella vaccine,</p> <p>19 correct?</p> <p>20 A. That is correct.</p> <p>21 Q. The rubella vaccine is manufactured by a</p> <p>22 pharmaceutical company or companies, correct?</p> <p>23 A. That is correct.</p> <p>24 Q. Was it better for CDC to do that as you</p> <p>25 did or for the pharmaceutical companies to do that?</p>	<p style="text-align: right;">Page 79</p> <p>1 Q. October of?</p> <p>2 A. '67. Usually it's counted as starting in</p> <p>3 December -- I mean January 1 of '68 but it literally</p> <p>4 started in '67.</p> <p>5 Q. So that was well underway when you came to</p> <p>6 CDC?</p> <p>7 A. It was.</p> <p>8 Q. And you took over the running of it at a</p> <p>9 certain time when you were at CDC, correct?</p> <p>10 A. When I first came to CDC I was the person</p> <p>11 who went out to the hospital and collected records.</p> <p>12 Q. But who was in charge of the CDC Atlanta</p> <p>13 registry when you were chief of the Birth Defects</p> <p>14 Division at CDC?</p> <p>15 A. Oh, it was under me, sure.</p> <p>16 Q. Now, did that registry collect drug usage</p> <p>17 information from the women whose medical information</p> <p>18 was collected?</p> <p>19 A. As I had said earlier, it is common for a</p> <p>20 birth defects registry to provide the cases for a</p> <p>21 case control study and in fact we used many of the</p> <p>22 cases to do a case control study.</p> <p>23 Q. That's not an answer to my question,</p> <p>24 Doctor. Did that registry collect drug usage</p> <p>25 information from the women whose medical information</p>
<p style="text-align: right;">Page 78</p> <p>1 A. Either could have --</p> <p>2 MS. BRAHMBHATT: Objection, form.</p> <p>3 A. -- done it well. Either could have done</p> <p>4 it well.</p> <p>5 Q. (By Mr. Strain) Why did CDC do it?</p> <p>6 A. CDC has a huge immunization program and</p> <p>7 lots of money.</p> <p>8 Q. Now, the Atlanta registry is a birth</p> <p>9 defect registry, correct?</p> <p>10 A. It is.</p> <p>11 Q. You were involved with that for many</p> <p>12 years, correct?</p> <p>13 A. That is correct.</p> <p>14 Q. Is there any exposure registry you were</p> <p>15 involved with?</p> <p>16 A. Other than asking Dr. Lammer to set up and</p> <p>17 collect cases related to Accutane.</p> <p>18 Q. So other than that, no, you weren't</p> <p>19 involved -- you didn't have any involvement with an</p> <p>20 exposure registry; is that correct?</p> <p>21 A. That's correct.</p> <p>22 Q. Now, let's talk about the birth defect</p> <p>23 registry in Atlanta. That was started when, Doctor?</p> <p>24 A. It started in October of</p> <p>25 nineteen-eighty -- '67.</p>	<p style="text-align: right;">Page 80</p> <p>1 was collected?</p> <p>2 A. The Atlanta birth defects registry form</p> <p>3 was primarily getting the name of the defect and the</p> <p>4 family name and what was known about what could be</p> <p>5 gotten from a casual viewer looking at the chart.</p> <p>6 But the way we looked for to do our etiologic</p> <p>7 research was primarily through the case control</p> <p>8 studies.</p> <p>9 Q. Well, let's look at something from The</p> <p>10 Lancet in November of '82 I think it is. We'll mark</p> <p>11 this as the next exhibit which I believe is 12.</p> <p>12 (Defendant's Exhibit 12 was marked</p> <p>13 for identification.)</p> <p>14 Q. (By Mr. Strain) This is a Lancet letter</p> <p>15 dated November 13, 1982. You're one of the authors</p> <p>16 of this, Doctor?</p> <p>17 A. Yes.</p> <p>18 Q. Did you actually write it?</p> <p>19 A. I drafted it.</p> <p>20 Q. You refer both in the chart and in the</p> <p>21 text of the letter to the Atlanta registry.</p> <p>22 A. Yep.</p> <p>23 Q. It says in the chart the Atlanta, that's a</p> <p>24 reference to the Atlanta registry we've been</p> <p>25 discussing, right?</p>

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<p style="text-align: right;">Page 89</p> <p>1 help determine the risk of valproate therapy to 2 women of childbearing years? 3 A. I would say once it was established as a 4 teratogen, which it was in '82, we thought that was 5 established. And as I had said earlier, we had 6 birth defects registry during these years. We got I 7 think it was a letter from 50 senators to do a study 8 on whether Vietnam veterans caused birth defects or 9 not. We put a lot of energy into doing that. That 10 was a wide-based questionnaire that had many things 11 in it including risk for anticonvulsants, so that 12 was done in that study. But the primary motivation 13 for doing that was the fact that veterans thought 14 that Agent Orange had caused birth defects. 15 Q. Doctor, in the early part of your answer 16 you said it was established that valproic acid was a 17 teratogen in 1982. Of what significance was that in 18 terms of what you were going to do or not do with 19 the Atlanta registry? 20 A. Well, to me it meant -- there aren't many 21 human teratogens. 22 Q. All right. 23 A. So there was Thalidomide. And along came 24 valproic acid, a new human teratogen. And as sort 25 of a way to just keep up with that we offered to do</p>	<p style="text-align: right;">Page 91</p> <p>1 A. It is a birth defects registry. It is not 2 an exposure registry. So a birth defects registry 3 starts with birth defects and we can learn about 4 potential risk factors for birth defects. But it 5 wouldn't tell us anything about spina -- about 6 cerebral palsy or mental retardation or loss of IQ 7 points or autism or other things. But if you had an 8 exposure registry, then you added people who were 9 exposed and you can follow them up for many 10 different outcomes including birth defects. 11 Q. Did you use the Atlanta registry in any 12 way to determine birth defect risk from valproate 13 usage? And if so, how? 14 A. I believe that in the last five years the 15 expanded network of birth defect surveillance 16 programs has published a paper looking at the risk 17 for spina bifida or for birth defects in valproic 18 acid and they found the association again with 19 spina bifida. And I think there's a paper there 20 that estimated sort of 40 or 50 patients with 21 valproic acid a year caused spina bifida. 22 Q. So you said that was in the last five 23 years, so let me modify my question. You left the 24 CDC in 1988, correct? 25 A. That's correct.</p>
<p style="text-align: right;">Page 90</p> <p>1 this registry. It didn't go anywhere. 2 Q. So what difference does it make that it 3 was established as a teratogen? Do you mean it was 4 time then to move on -- 5 A. I thought -- 6 Q. -- to other things? 7 A. -- the drug should come off the market. 8 MS. BRAHMBHATT: Let him finish. 9 THE WITNESS: I'm sorry. 10 Q. (By Mr. Strain) What did you mean then it 11 was established as a teratogen, Doctor? Does it 12 mean then that it wasn't necessary to do further 13 work at CDC with your registry about valproic acid? 14 A. We were a birth defects registry. That 15 was our primary issue. We did at that time not have 16 work in developmental disabilities. And so, you 17 know, our focus was on birth defects. And we didn't 18 know what we might learn from a registry like that 19 but if we had it in place we might learn some more 20 things. 21 Q. But Doctor, you didn't use the Atlanta 22 registry to attempt to determine more things about 23 valproic acid, did you? 24 A. That's not true. 25 Q. How did you use it?</p>	<p style="text-align: right;">Page 92</p> <p>1 Q. Were you chief of the Birth Defects 2 Branch -- 3 A. I was. 4 Q. -- until you left? 5 A. I was. 6 MS. BRAHMBHATT: Let him finish the 7 question. 8 Q. (By Mr. Strain) While you were chief of 9 the Birth Defects Branch until 1998, did you use the 10 Atlanta registry to determine and to find out 11 anything about birth defects with valproic acid? 12 A. We were collecting data in the Atlanta 13 situation -- in the Atlanta area and in five other 14 different states. And in collecting -- doing a case 15 control study on those I collected various 16 information. And as I said, it is a while before it 17 gets analyzed. And there was an analysis after I 18 left CDC from this exposure -- from this birth 19 defects registry in which we were collecting 20 exposure data. 21 Q. Is this right: Though you were working on 22 that since 1982, you did not have the data gathered 23 and analyzed in time to publish it before 1998; is 24 that correct? 25 A. No.</p>

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<p style="text-align: right;">Page 101</p> <p>1 since then. And so I don't think I could give you 2 an answer today. 3 Q. Well, did you recommend that the 4 manufacturer of Valium establish an exposure 5 registry? 6 A. Well, when we were publishing not this 7 paper but The Lancet paper I did call the scientific 8 director of Roche at the time and tell him we were 9 publishing this paper and I was absolutely floored 10 that the most widely-prescribed prescription in the 11 world they didn't have any exposed pregnant women in 12 it to help us inform this decision. That was when I 13 first thought why do not drug companies when they're 14 going to use a drug that's widely exposed identify 15 cohorts of women that have been exposed so they have 16 in their own data data that can be compared to 17 people who come up with a hypothesis. 18 Q. In that answer you mean you were floored 19 to find out that in their clinical trials of Valium 20 there have not been -- pregnant women have not 21 been enrolled? 22 A. That's not what I said. 23 MS. BRAHMBHATT: Objection, form. 24 Q. (By Mr. Strain) What did you mean then? 25 A. What I said was this drug, which was</p>	<p style="text-align: right;">Page 103</p> <p>1 an exposure registry? 2 A. That I don't know. 3 Q. Did you recommend that they do so? 4 A. I didn't recommend that they do so, no. 5 Q. Why not? 6 A. We were trying to settle the question of 7 whether this is a human teratogen or not a human 8 teratogen and the most efficient way to do that was 9 to do a case control study. 10 Q. Did you believe that a manufacturer 11 pregnancy registry for Valium would provide useful 12 and important information? 13 A. I think it could have, yes. 14 Q. And so why didn't you recommend that Roche 15 establish that? You've already said it was the 16 largest-selling drug in the world. 17 MS. BRAHMBHATT: Asked and answered. 18 Objection, form. 19 A. I don't know. 20 Q. (By Mr. Strain) When did you first have 21 any experience with a manufacturer-sponsored or 22 created exposure registry? Was that the rubella -- 23 no, I'm sorry, that wasn't the rubella. So the 24 question is when did you first -- I'm starting 25 over -- when did you first have any experience with</p>
<p style="text-align: right;">Page 102</p> <p>1 widely marketed, when I asked them if they had an 2 exposure registry or had any women and knew what the 3 rates of birth defects were among women that were 4 exposed, they said no. And from that moment on I 5 thought why in the world would a drug company sell a 6 drug that was going -- that women who would get 7 inadvertently pregnant not find out what happened to 8 those pregnancies so that when someone raised a 9 hypothesis like Safra and Oakley, they would have 10 their own data to be able to say this is what we 11 found or not found. But it just wasn't part -- it 12 didn't happen. It wasn't there. 13 Q. Did you recommend to Roche pharmaceutical 14 company they start an exposure registry for Valium? 15 A. Roche on its own decided to go to the 16 people in Boston to test this hypothesis in a 17 different set. Absolutely they did that, yes. 18 Q. In a what? 19 A. In a case control study in Boston. They 20 went and paid -- and actually funded it. And I was 21 on an advisory committee in which that study as 22 done. 23 Q. And what did that study determine? 24 A. That study turned out to be negative. 25 Q. Did Roche establish a pregnancy registry,</p>	<p style="text-align: right;">Page 104</p> <p>1 or involvement with a manufacturer-sponsored 2 exposure registry for the manufacturer's drug? 3 A. I suppose it was with Dr. Cragen's work 4 with probably first one of the AIDS drugs. 5 Q. And when was that? 6 A. I can't tell you exactly but in the 7 eighties sometime I would guess. 8 Q. So other than the AIDS drugs -- and that 9 was Dr. Cragen, not you; is that right? 10 A. Yeah. She worked for me but she was the 11 one that took that on, yes, and Dr. Cordero who 12 worked for me for a while was involved. I mean at 13 the CDC we had the issue of they were using drugs to 14 treat AIDS, using drugs to treat VD, we thought they 15 ought to be looking at whether they caused birth 16 defects or not. 17 Q. When else did you have any involvement 18 with a manufacturer-sponsored exposure registry of 19 one of its drugs? 20 A. I don't think that I did. As I said 21 earlier, when this paper came up it was crystal 22 clear to me there would be a very good idea if they 23 had them but I didn't think it was my job 24 necessarily to build that. I mean I would have been 25 happy -- I talked around with -- I would have been</p>

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1 happy if the drug companies had said hey, come to  
2 CDC and do these registries. They didn't do that.  
3 They didn't do it themselves.  
4 Q. So when you say this paper in that last  
5 answer, you referred to and pointed to Exhibit 13 --  
6 A. Yes.  
7 Q. -- about Valium --  
8 A. Yes.  
9 Q. -- correct?  
10 Other than the AIDS drugs what  
11 manufacturer-sponsored registries of drugs existed  
12 in the eighties or nineties?  
13 A. I don't know.  
14 Q. Did any others exist --  
15 A. They may have.  
16 Q. -- in the eighties --  
17 A. They may have.  
18 Q. -- or nineties?  
19 MS. BRAHMBHATT: Let him finish.  
20 THE WITNESS: Sorry.  
21 (A recess was had.)  
22 Q. (By Mr. Strain) Did you determine that  
23 Diazepam may be a teratogen?  
24 A. We certainly identified an association and  
25 raised that question.

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1 Q. Is Diazepam a teratogen?  
2 A. I think it is still unresolved. But I  
3 haven't looked at the data in a very long time.  
4 Q. Who manufactures Diazepam?  
5 A. Roche.  
6 Q. Did you ask Roche to start a registry  
7 about Diazepam?  
8 A. I did not.  
9 Q. And why didn't you?  
10 A. Because they decided to undergo some  
11 studies in Boston and that was a reasonable first  
12 step.  
13 Q. Well, there were studies. Did you believe  
14 it would have been a good idea for them to have a  
15 registry in addition to studies?  
16 A. Yes, I think it would have been a good  
17 idea. From the very time they first issued -- they  
18 were first approved to sell the drug I believe they  
19 should have had a registry of exposed pregnant  
20 women.  
21 Q. Did you believe that as to all drugs to be  
22 used by pregnant women?  
23 A. I do.  
24 Q. Valproate, Valium, Diazepam, Tegretol,  
25 phenobarbital, all of them, correct?

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1 A. Every one of them.  
2 Q. How many do?  
3 A. I don't know.  
4 Q. So there must be what, 50, a hundred, 200  
5 drugs used by pregnant women?  
6 A. Yes.  
7 Q. You believe all of them should have a  
8 pregnancy registry?  
9 A. That's the most effective way to find  
10 adverse effects from a new drug being introduced.  
11 Q. So how many of those many, many, many  
12 drugs used by pregnant women do have pregnancy  
13 registries?  
14 A. I don't know the answer to that question.  
15 Q. Do any drugs used by pregnant women  
16 introduced in the 1980s have a pregnancy registry?  
17 A. I don't know the answer to that question.  
18 Q. You never worked for a pharmaceutical  
19 company, correct?  
20 A. That is correct.  
21 Q. And you never received any information  
22 about what sales representatives do or their  
23 training or anything like that, correct?  
24 A. I don't recall any.  
25 Q. And you have no knowledge of what the FDA

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1 regulations are concerning what sales  
2 representatives are permitted to do or not permitted  
3 to do, correct?  
4 A. That's correct.  
5 Q. Do you have any knowledge of what the  
6 educational background is of sales representatives  
7 generally?  
8 A. Just from the few I know they usually have  
9 college degrees.  
10 Q. Usually have?  
11 A. College degrees.  
12 Q. But they're not healthcare professionals?  
13 A. I don't know how they would describe  
14 themselves.  
15 Q. Can you give me an example of any  
16 manufacturer of a product who's used its sales  
17 representatives as part of a pregnancy exposure  
18 registry?  
19 A. It seems to me that those people who are  
20 in doctors' offices could have for a relatively  
21 small part of their time identified exposed women.  
22 Q. I'm just asking the question -- we'll get  
23 to that -- the question was can you give me an  
24 example of where that's ever been done?  
25 A. I'm not aware of it.

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1 Q. (By Mr. Strain) Dr. Oakley, you never  
2 wrote down anything about the parameters or rules or  
3 protocol or outline of the registry that you propose  
4 Abbott should have done in the eighties or nineties,  
5 correct?  
6 A. That is correct.  
7 Q. And you never calculated how many people  
8 would have to be enrolled and how many women using  
9 valproate monotherapy in the first trimester would  
10 have had to be enrolled to get meaningful  
11 information, correct?  
12 MS. BRAHMBHATT: Objection, form.  
13 A. That's correct.  
14 Q. (By Mr. Strain) Did you ever calculate how  
15 long it would have taken to get sufficient  
16 enrollment to get meaningful information?  
17 A. I did not.  
18 Q. And do you know how long it would have  
19 taken without having calculated it to get sufficient  
20 enrollment to get meaningful information?  
21 A. No.  
22 Q. And I think you've already said you never  
23 designed a pharmaceutical company exposure registry,  
24 correct?  
25 A. That's correct.

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1 Q. And you never designed any registry for  
2 the CDC or for anybody else specific to a given  
3 drug, correct?  
4 A. You mean an exposure --  
5 MS. BRAHMBHATT: Objection, form.  
6 A. You mean an exposure registry?  
7 Q. (By Mr. Strain) Yes, sir.  
8 A. That's correct.  
9 Q. And the only effort to do so was the  
10 effort we've talked about described in the two MMWR  
11 publications in '82 and '83, correct?  
12 A. Would you say that again.  
13 Q. The only effort you were involved in to  
14 create an exposure registry of a specific drug was  
15 what we have talked about in the two MMWR sheets in  
16 1982 and 1983, correct?  
17 A. No. As I said earlier, I asked Ed Lammer  
18 to try to find kids that had been exposed to  
19 Accutane and follow them up.  
20 Q. Other than that? But I think you've made  
21 clear that was Dr. Lammer's project, not yours?  
22 A. But he was under me when it got started  
23 and I certainly was happy to see him do that. And  
24 the ideas of starting it were to find out what we  
25 can find out about this exposure.

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1 Q. Did you have involvement or did you  
2 supervise or review Dr. Lammer's work --  
3 A. In the first part --  
4 Q. -- in that rubella registry?  
5 A. Dr. Lammer was not involved in the rubella  
6 registry.  
7 Q. Excuse me, the Accutane registry.  
8 A. Yeah. Yes, I was his supervisor for -- he  
9 worked under me for probably the first year that he  
10 worked on it but not the last two years.  
11 Q. Well, what was your personal involvement?  
12 A. I said I agreed that this registry ought  
13 to be -- that he thought to go find as many people  
14 as he could that had been exposed to this drug and  
15 try to learn what we could learn from those people.  
16 Q. Have you done any calculation of what the  
17 likely result would have been if Abbott had started  
18 a registry of the kind you proposed in the 1980s or  
19 nineties?  
20 A. I have entertained that thought in  
21 thinking about how big you would have to expose a  
22 1 percent event, you know, it would be nice to have  
23 500 to a thousand.  
24 Q. And have you determined what the result  
25 would have been if Abbott had established such a

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1 registry as you recommend?  
2 MS. BRAHMBHATT: Objection, form.  
3 A. I don't know how to answer that question.  
4 Ask again, please.  
5 Q. (By Mr. Strain) What would the result have  
6 been if Abbott had established a registry of the  
7 kind you recommended back in the 1980s?  
8 A. The recommendation is if it is established  
9 when the first prescription is written, it would  
10 decrease the time at which the public health and  
11 physicians community would know that the drug caused  
12 spina bifida. It could have been found out before  
13 1982, you know, if it had been established in France  
14 in 1967. So those registries would have found it  
15 earlier than it was found. We did find it. We  
16 might not have ever found it if it hadn't been for  
17 the widespread use in France.  
18 Q. So the registry you recommend would have  
19 been a spina bifida registry --  
20 A. No.  
21 Q. -- is that correct?  
22 A. I'm sorry. I interrupted again.  
23 Q. What would it have been?  
24 A. It would have been -- it would have been  
25 an exposure registry in which ideally with women

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<p style="text-align: right;">Page 125</p> <p>1 compare what one manufacturer could do in a registry 2 with what EUROCAT did based on a group of 3 government-funded registries in Europe. Can you 4 explain that to me. 5 A. I can try. The European registries are 6 like the Atlanta registry, they counted babies with 7 birth defects and then they have to find out about 8 the exposure. If you started the other way, you'd 9 start out and you'd have your indication of the 10 exposure and you would follow those people up. And 11 you would have to have a lot of exposed people, no 12 question about that. 13 Q. Did you have any involvement in the NEAD 14 study? 15 A. I don't think I had any involvement 16 although I may have been a reviewer on behalf of NIH 17 at some time during one of the projects that 18 Dr. Holmes worked on. 19 Q. The NEAD study is where you're referring 20 to Dr. Holmes' study? 21 A. Maybe I got the acronym wrong, so please 22 tell me. 23 Q. I'm not talking about the North American 24 antiepileptic drug registry. Was there a study -- 25 A. You are or you are not?</p>	<p style="text-align: right;">Page 127</p> <p>1 Q. How long did it take for Dr. Meador and 2 others working on that to get a sufficient number of 3 enrollees to get meaningful results? 4 A. I don't know. 5 MS. BRAHMBHATT: Objection, form. 6 Q. (By Mr. Strain) Are you able to describe 7 that study to us, Doctor? 8 A. I could tell you some things about it. 9 Q. Please do. 10 A. Well, it was an attempt to find women that 11 had been exposed to monotherapy I guess before 12 anticonvulsants and to attract those and to follow 13 the outcomes of those pregnancies. 14 Q. Did the Atlanta registry with which you 15 were involved, did that gather information about 16 cognitive development? 17 A. No. 18 Q. Did the 1,200 hospital registry with which 19 CDC was involved gather information about cognitive 20 development? 21 A. No. 22 Q. And why didn't the Atlanta registry gather 23 information about cognitive development? 24 A. It was a small operation. Its idea was to 25 do birth defects surveillance. There had been the</p>
<p style="text-align: right;">Page 126</p> <p>1 Q. I'm not. 2 A. I'm sorry. 3 Q. Was there a study run out of Emory 4 University with which you're affiliated called the 5 NEAD study of cognitive impact of antiepileptic 6 drugs? 7 A. Yes. 8 Q. Did you have any involvement with that 9 study? 10 A. I did not. 11 Q. And who was the principal investigator on 12 that study? 13 A. Dr. Meador. 14 Q. I guess in your field, Doctor, your being 15 at Emory I'm surprised you didn't have any 16 involvement. Why was that? 17 A. Well, he was the PI. I think he actually 18 started that study before he came to Emory. 19 Q. And when did he come to Emory? 20 A. I would guess about ten years ago but I 21 don't know. I was there several years before I met 22 him. 23 Q. And you've been there since '98; is that 24 correct? 25 A. Yes.</p>	<p style="text-align: right;">Page 128</p> <p>1 Thalidomide epidemic which you must be aware of. 2 That prompted us putting into place a birth defects 3 registry trying to look for the next epidemic of an 4 environmental agent. Subsequently to that we set up 5 a different program that does relate to cerebral 6 palsy and mental retardation. 7 Q. And when did you set that up? 8 A. In the middle eighties I think it was. 9 Q. The CDC did? 10 A. Yes. 11 Q. And what was the registry called? 12 A. It has an acronym NASPA, N-A-S-P-A I think 13 it was. 14 Q. And please describing that registry for 15 me. 16 A. It was a registry based on school records 17 is where the case ascertainment was and it was for 18 mental retardation, cerebral palsy, blindness, 19 deafness. I've missed one which I've just 20 forgotten. And later this group of people added 21 autism. 22 Q. Was it an attempt to determine the causes 23 of cerebral palsy and mental retardation and 24 blindness and deafness? 25 A. Yes.</p>

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<p style="text-align: right;">Page 141</p> <p>1 Q. Can you tell me any company that did that</p> <p>2 about a prescription drug back in the eighties?</p> <p>3 A. I would be uninformed on that.</p> <p>4 Q. Can you tell me any company that did that</p> <p>5 about a prescription drug in the 1990s?</p> <p>6 A. But again, it is not something that I'm</p> <p>7 really fully informed on. But I don't have any -- I</p> <p>8 don't know of any but there might be.</p> <p>9 Q. Can you tell me of any registry at all,</p> <p>10 whether prescription drug or not, in the eighties or</p> <p>11 nineties that attempted to determine the cognitive</p> <p>12 impact of any environmental factor of children born</p> <p>13 and then follow them through ages two, three, five,</p> <p>14 six, or older?</p> <p>15 A. Yes.</p> <p>16 Q. What's that, please?</p> <p>17 A. So the collaborative perinatal study was</p> <p>18 done in the late sixties and cohortive 50,000</p> <p>19 pregnancies were assembled and they were followed</p> <p>20 through until at least age five. I don't know how</p> <p>21 much longer. And there were sort of case</p> <p>22 control-like analyses done out of that.</p> <p>23 Q. What study did you say that was?</p> <p>24 A. It was the collaborative perinatal study</p> <p>25 it was called, the National Collaborative Perinatal</p>	<p style="text-align: right;">Page 143</p> <p>1 A. My opinion is that an exposure registry of</p> <p>2 women -- pregnant women exposed to valproic acid</p> <p>3 could have been set up in 1965 when the drug was</p> <p>4 first put on the market in France and those children</p> <p>5 followed up appropriately. We'd have learned things</p> <p>6 sooner than Meador learned them in the last ten</p> <p>7 years. If we'd have done that, we would have found</p> <p>8 it sooner.</p> <p>9 Q. Now, if you had done what Meador did?</p> <p>10 A. Kim Meador.</p> <p>11 Q. Kim Meador?</p> <p>12 A. Yes.</p> <p>13 Q. Is that what in your opinion Abbott should</p> <p>14 have done --</p> <p>15 A. I don't see why not.</p> <p>16 Q. -- a study like -- excuse me.</p> <p>17 A. Sorry.</p> <p>18 Q. A registry just like Meador?</p> <p>19 A. I don't see any problem with having set up</p> <p>20 a forward-going exposure registry and then you'd</p> <p>21 have to decide what would be the control groups and</p> <p>22 yes, they'd have -- whether it be exactly the same</p> <p>23 kind of study. I doubt it would be exactly the same</p> <p>24 kind of study, but it certainly could be something</p> <p>25 rather similar to it.</p>
<p style="text-align: right;">Page 142</p> <p>1 Study. It was run out of NIH. And the kids or the</p> <p>2 births were I think mid to late seventies and they</p> <p>3 were followed up and there were studies written</p> <p>4 about the IQ of these kids at five years and so on.</p> <p>5 Q. But that was a government-funded NIH</p> <p>6 study?</p> <p>7 A. It was, yeah.</p> <p>8 Q. Did that study attempt to determine the</p> <p>9 effect of environmental factors such as prescription</p> <p>10 drugs on IQ?</p> <p>11 A. I don't know all the things that they did.</p> <p>12 It was a large study and there were many, many, many</p> <p>13 papers published out of that. And I would be</p> <p>14 surprised if there weren't but I don't know the</p> <p>15 answer.</p> <p>16 Q. Well, did that study lend itself to</p> <p>17 determining the effect on IQ of antiepileptic drug</p> <p>18 usage?</p> <p>19 A. It would be a function of how much</p> <p>20 exposure it was in that cohortive 50,000. And</p> <p>21 without knowing that, I can't do anymore.</p> <p>22 Q. Well, you have suggested that Abbott</p> <p>23 should have had a registry to determine cognitive</p> <p>24 impact way back in the eighties; is that your</p> <p>25 opinion?</p>	<p style="text-align: right;">Page 144</p> <p>1 Q. Now, why do you doubt it would have been</p> <p>2 exactly the same kind of study?</p> <p>3 A. Because two people don't usually design</p> <p>4 the same studies. Two different people would have</p> <p>5 different ...</p> <p>6 Q. You have just used the term Meador study.</p> <p>7 Meador really did a study rather than a registry,</p> <p>8 correct?</p> <p>9 A. Well, he attracted -- as I understand it</p> <p>10 he attracted women who were exposed in pregnancy to</p> <p>11 these four drugs and then he wanted to have a</p> <p>12 control group but NIH wouldn't fund a control group</p> <p>13 so we didn't have a normal control group. That's</p> <p>14 why he makes these comparisons between the other</p> <p>15 monotherapy.</p> <p>16 Q. Why didn't NIH fund the control group?</p> <p>17 A. I have no idea. They thought -- I don't</p> <p>18 know.</p> <p>19 Q. But he simply went around the</p> <p>20 Massachusetts area hospitals to identify patients</p> <p>21 who had used antiepileptic drugs during pregnancy,</p> <p>22 correct?</p> <p>23 A. Let's make sure we got the right guy. So</p> <p>24 we're talking the guy from Emory, right?</p> <p>25 Q. Yes.</p>

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<p>Page 157</p> <p>1 effects on their drug.</p> <p>2 Q. You don't know whether other drug</p> <p>3 companies would have been willing to participate?</p> <p>4 A. I do not know that.</p> <p>5 Q. In the study that you believe Abbott</p> <p>6 should have undertaken in the 1980s, would that have</p> <p>7 been one study for birth defects and cognitive</p> <p>8 impact or two different studies?</p> <p>9 A. Well, it would be an exposure registry.</p> <p>10 And so if you define this as an exposure registry,</p> <p>11 it is an exposure registry and you go look at</p> <p>12 multiple outcomes.</p> <p>13 Q. Well, then I have to ask you whether</p> <p>14 there's any precedent for that, Doctor. The Holmes</p> <p>15 study, the North American antiepileptic drug</p> <p>16 registry study is only a birth defects and not</p> <p>17 cognitive impact, correct?</p> <p>18 A. I'm not sure that's true. He certainly</p> <p>19 has the capacity to look at cognitive issues if he's</p> <p>20 been interested in cognitive issues.</p> <p>21 Q. So you think Dr. Holmes's group gathered</p> <p>22 information on cognitive impact at age one year,</p> <p>23 three years, five years, and the rest?</p> <p>24 A. I don't remember the details. But I am</p> <p>25 unwilling to say he didn't do it. I would think</p>	<p>Page 159</p> <p>1 forever.</p> <p>2 Q. Any others?</p> <p>3 A. The atomic bomb study did it.</p> <p>4 Q. The atomic bomb study and the</p> <p>5 collaborative perinatal study. Any others?</p> <p>6 A. Yes. I mean they're both exposure studies</p> <p>7 and they could go out.</p> <p>8 Q. Any others?</p> <p>9 A. I haven't exhaustively tried to answer</p> <p>10 that question. There probably are others but I</p> <p>11 don't know exactly what they are.</p> <p>12 Q. They were both government-funded studies,</p> <p>13 correct?</p> <p>14 A. They were.</p> <p>15 Q. Can you give me any example of a</p> <p>16 privately-funded by a pharmaceutical company or</p> <p>17 anybody else study that measured both birth defects</p> <p>18 and cognitive impact?</p> <p>19 A. I know that Roche hired guys in Boston to</p> <p>20 do Accutane. And how far they followed them I don't</p> <p>21 know but they certainly had the possibility once</p> <p>22 they've identified women who were exposed to</p> <p>23 Accutane in pregnancy to follow their kids. And I</p> <p>24 actually think maybe there were some cognitive</p> <p>25 studies done in that but I'm not certain.</p>
<p>Page 158</p> <p>1 they might have done that I don't know.</p> <p>2 Q. Well, if he did it, why was it necessary</p> <p>3 for Meador to do it?</p> <p>4 MS. BRAHMBHATT: Objection, form.</p> <p>5 A. Again I have not reviewed recently all of</p> <p>6 the stuff out of that study. So you asked that</p> <p>7 question and I tried to answer the best I could.</p> <p>8 Q. (By Mr. Strain) I wonder if you'd tell me</p> <p>9 this, Doctor: Can you give me one example of a</p> <p>10 study of antiepileptic drugs that measured both</p> <p>11 cognitive impact and birth defects?</p> <p>12 A. I think that Meador identified in his</p> <p>13 study spina bifida. I have to go back and -- not in</p> <p>14 this paper but in a different paper because I know</p> <p>15 he's told me that early on in conversation but I</p> <p>16 don't remember the paper. But the point is if you</p> <p>17 have got an exposure registry, whatever question</p> <p>18 comes up about an outcome, you can ask it. If you</p> <p>19 start with an outcome registry, you can ask about an</p> <p>20 infinite number of exposures.</p> <p>21 Q. I'm just asking, Doctor, whether you could</p> <p>22 give me any precedent for that having been done both</p> <p>23 birth defects and cognitive impact in the same</p> <p>24 study?</p> <p>25 A. The collaborative perinatal study did that</p>	<p>Page 160</p> <p>1 Q. Are you prepared to tell me whether the</p> <p>2 study you believe Abbott should have done is similar</p> <p>3 to the study that was done on Accutane or different?</p> <p>4 A. It would be similar in the fact that you'd</p> <p>5 have to try to find exposed women during their</p> <p>6 pregnancy and then follow them up. And Roche made a</p> <p>7 fairly large attempt to do that as I understand it.</p> <p>8 Q. I'm just looking for something, Doctor, in</p> <p>9 the definition of what you say Abbott should have</p> <p>10 done if you can identify a study and tell me Abbott</p> <p>11 should have done that study.</p> <p>12 A. Well, what I think Abbott should have done</p> <p>13 was to sit down in 1982 and say we have a drug that</p> <p>14 causes birth defects, shouldn't we find out, if</p> <p>15 we're going to continue to keep this drug on the</p> <p>16 market, shouldn't we try to find out if it has any</p> <p>17 other adverse effects.</p> <p>18 Q. Not my question, Doctor. I'm asking if</p> <p>19 you can point to a study that you can say Abbott</p> <p>20 should have done a study just like that and that</p> <p>21 would give me definition, concreteness to what</p> <p>22 you're suggesting Abbott should have done. Can you</p> <p>23 point to such a study?</p> <p>24 A. There are plenty of exposure registries</p> <p>25 and it would be easy for somebody to pick up and do</p>